REMARKS

The present invention is directed to an improved, child-resistant medicament container.

There is provided an apparatus comprising a circular or substantially circular medicament container. The medicament container comprises a plurality of medicament cells preferably containing contents to be dispensed and retained in a housing having a single dispensing aperture. The medicament container is rotatably mounted in, or on, the housing about a common axis such that the medicament container may be moved between a freely rotatable, non-dispensing position, and a locked, non-rotating dispensing position. By providing such housing having a single dispensing aperture and means for locking the medicament container in a locked, non-rotating dispensing position, only contents contained in a single medicament cell may be dispensed through the dispensing aperture in a single operation of the device, even though the medicament container incorporates a plurality of medicament cells containing contents to be dispensed.

The claims pending in this application number 1 through 5.

Claim 1 has been rejected under 35 USC 112, second paragraph for indefiniteness. Claim 5 has been rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The rejections are respectfully traversed.

The first paragraph of 35 USC 112 requires that

> [t]he specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

With respect to the first paragraph of 112, the severability of its written description provision from its enablement provision was recognized long ago in re Ruschig, 154 USPQ 118 (CCPA 1967):

> [T]he question is not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented....If [the rejection is] based on section 112, it is on the requirement thereof that "[T]he specification shall contain a written description of the invention ..." Ruschig at 123. The issue, as the court saw it, was one of fact: "Does the specification convey clearly to those skilled in the art, to which it is addressed, in any way, the information that appellants invented that specific compound?" Ruschig at 123.

Whether a specification contains a sufficient disclosure under 35 USC 112 is one of law; compliance with the written description is one of fact. Utter v. Hiraga, 6 USPQ2d 1709 (Fed. Cir. 1988).

In rejecting Claim 1, the Examiner, at page 2 of the Office Action, states 'Claim 1 on line 4 recites "a circular --- container". Should not "a" be recited as -said-, as the structure has already been recited in lines 2 and 3.'

The Examiner's attention is respectfully directed to pending Claim 1. Claim 1 describes a housing and a circular container inside the housing. The invention consists of both components together – a housing and a circular container. Claim 1 distinctly claims 1) the "rotatable, non-dispensing" feature of the invention, which is important for child-resistance since no medicament can be accidentally or intentionally taken by a child, and 2) the dispensing non-rotatable feature, which requires the dexterity of an adult to position the circular container. The container is not rotatable at the dispensing position and, when in the dispensing position, only one medicament can be dispensed. Again, this prevents a child from accessing the rest of the medicaments if the device is left in the dispensing position.

With respect to Claim 5, the Examiner states, "...it is noted on page 11 of the specification and in figure 1c that the projections engage one of the blister cells so that rotation of the blister package is blocked. However, as noted in figure 1c, with the blister cell in between the projections 15, it is not clearly understood how the blister package would be capable of rotation to another dispensing position."

The Examiner's attention is respectfully directed to page 9, line 26 through page 10, line 8 of the specification where the practice of the invention is fully explained. As shown in Figure 1a, the projections (15) prevent the blister cells from rotating in the dispensing position. The circular container must be moved from the non-dispensing, rotatable position to the non-rotatable dispensing position. At page 9, line 32 through page 10, line 7 of the specification, Applicant clearly states

> ...which is disengageable there from, preferably by means of downwardly depending pressure exerted by, for example, a finger of the user. In the exemplary embodiment shown in Fig. 1a, the common axis 11 comprises a spindle member constructed integrally with, or comprising an excised segment of, the bottom section 1b of the housing. The operational steps of disengaging the blister package from the common axis 11, moving the blister package into the dispensing position, and dispensing the articles 9 contained therein through the dispensing aperture 10, are depicted sequentially in FIG 1b.

Applicant submits the pending claims are clear and understandable on their face to a skilled individual and fully comply with the statutory requirements of 35 USC 112. Withdrawal of all rejections under 35 USC 112 is respectfully requested.

Claims 1-4 have been rejected under 35 USC 102(b) as being anticipated by Studer (U.S. 4,165,709). Claims 1-4 have also been rejected under 35 USC 102(b) as being anticipated by Lambert, Jr. Applicant presumes the rejection over Lambert, Jr. is a typographical error and that, in fact, the rejection is over Lambelet (U.S. 6,039,208). If the presumption is not correct, clarification of the rejection is requested so that Applicant may fully respond to the Examiner's concerns. Assuming the rejections are over Studer and Lambelet, the rejections are respectfully traversed.

It is well established that in order to sustain a finding of anticipation, all material elements of a claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CAFC 1978). Moreover, an inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities." Scaltech, Inc. v. Retec/Tetra, LLC, 51 U.S.P.Q.2d 1055, 1059 (Fed. Cir.1999). Additionally, in order to sustain a finding of anticipation, the disclosure of a prior art

reference must be adequate to enable possession of desired subject matter, and a reference that names or describes desired subject matter does not anticipate if the subject matter cannot be produced without undue experimentation. Even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. Elan v. Mayo Foundation, 68 USPQ2d 1373 (Fed.Cir. 2003).

Studer and others disclose a housing and a rotatable medication container. The locking in Studer's disclosure (col 12, lines 15-18) only prevents the medication container from reverse rotation; this feature is for keeping track of the dosing regimen. The remaining tablets can be individually dispensed (Abstract) by either an adult or a child, and therefore, the Studer device is not child-resistant. The locking feature of the present invention is to prevent dispensing in either forward or reverse rotation.

The comments above with respect to Studer are equally applicable to Lambelet. The present invention allows two distinct positions of the medication container inside the housing – non-dispensing, rotatable position and dispensing, non-rotatable, locking position.

The Examiner cites Richardson et al. as disclosing another type of rotatable blister package having a locking means. Again, the comments above with respect to Studer and Lambelet are equally applicable to Richardson et al. Richardson et al disclose a locking means to maintain the "chronological indicia" (Abstract) of the tablet dispenser. The dispensing and the locking position in Richardson et al. are the same in relation to the housing – unlike the present invention.

Studer, Lambelet, and Richardson et al. disclose means to chronologically dispense sequence specific medications, such as birth control pills. The "locking" means in the cited disclosures prevents reverse sequence dispensing. The scope of these disclosures is not for child-resistance. Child-resistant packaging for the type of medications in the cited inventions is not required according to Code of Federal Register. For the convenience of the Examiner, a copy of 16 CFR 1700.14, "Substances requiring special packaging" is attached.

Applicant's claimed invention is fully distinguished from the cited art. Withdrawal of all rejections under 35 USC 102 is requested.

This application is believed to be in condition for allowance. Favorable consideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§ 1.16 and 1.17, or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

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Carmella A. O'Gorman

Carmella A. O'Gorman
Attorney for Applicant(s)
Reg. No. 33,749

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 686-1847

ATTACHMENT

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

(1) *Aspirin.* Any aspirin-containing preparation for human use in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following:

(i) Effervescent tablets containing aspirin, other than those intended for pediatric use, provided the dry tablet contains not more than 15 percent aspirin and has an oral LD–50 in rats of 5 grams or more per kilogram of body weight.

(ii) Unflavored aspirin-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 15.4 grains of aspirin per unit dose and that contain no other substance subject to the provisions of this section.

(2) *Furniture polish.* Nonemulsion type liquid furniture polishes containing 10 percent or more of mineral seal oil and/or other petroleum distillates and having a viscosity of less than 100 Saybolt universal seconds at 100 °F., other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (d).

(3) *Methyl salicylate.* Liquid preparations containing more than 5 percent by weight of methyl salicylate, other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(4) *Controlled drugs.* Any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) and that is in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(5) *Sodium and/or potassium hydroxide.* Household substances in dry forms such as granules, powder, and flakes, containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(6) *Turpentine.* Household substances in liquid form containing 10 percent or more by weight of turpentine shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(7) *Kindling and/or illuminating preparations.* Prepackaged liquid kindling and/or illuminating preparations, such as cigarette lighter fuel, charcoal lighter fuel, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns, which contain 10 percent or more by weight of petroleum distillates and have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(8) *Methyl alcohol (methanol).* Household substances in liquid form containing 4 percent or more by weight of methyl alcohol (methanol), other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(9) *Sulfuric acid.* Household substances containing 10 percent or more by weight of sulfuric acid, except such substances in wet-cell storage batteries, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(10) *Prescription drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with

the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Sublingual dosage forms of nitroglycerin.

(ii) Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.

(iii) Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams of the equivalent of erythromycin.

(iv) Cyclically administered oral contraceptives in manufacturers' mnemonic (memory-aid) dispenser packages that rely solely upon the activity of one or more progestogen or estrogen substances.

(v) Anhydrous cholestyramine in powder form.

(vi) All unit dose forms of potassium supplements, including individually-wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit-dose packets, containing not more than 50 milliequivalents of potassium per unit dose.

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this § 1700.14(a)(10).

(viii) Betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams betamethasone.

(ix) Pancrelipase preparations in tablet, capsule, or powder form and containing no other substances subject to this § 1700.14(a)(10).

(x) Prednisone in tablet form, when dispensed in packages containing no more than 105 mg. of the drug, and containing no other substances subject to this § 1700.14(a)(10).

(xi)-(xii) [Reserved]

(xiii) Mebendazole in tablet form in packages containing not more than 600 mg. of the drug, and containing no other substance subject to the provisions of this section.

(xiv) Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug and containing no other substance subject to the provisions of this section.

(xv) Colestipol in powder form in packages containing not more than 5 grams of the drug and containing no other substance subject to the provisions of this section.

(xvi) Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.

(xvii) Conjugated Estrogens Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 32.0 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xviii) Norethindrone Acetate Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 50 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xix) Medroxyprogesterone acetate tablets.

(xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

(11) *Ethylene glycol.* Household substances in liquid form containing 10 percent or more by weight of ethylene glycol packaged on or after June 1, 1974, except those articles exempted by 16 CFR 1500.83, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(12) *Iron-containing drugs.* With the exception of: (i) Animal feeds used as vehicles for the administration of drugs, and (ii) those preparations in which iron is present solely as a colorant, noninjectable animal and human drugs providing iron for therapeutic or prophylactic purposes, and containing a total amount of elemental iron, from any source, in a single package, equivalent to 250 mg or more elemental iron in a concentration of 0.025 percent or more on a weight to volume basis for liquids and 0.025 percent or more on a weight to volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids

(e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(13) *Dietary supplements containing iron.* Dietary supplements, as defined in § 1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

(14) [Reserved]

(15) *Solvents for paint or other similar surface-coating material.* Prepackaged liquid solvents (such as removers, thinners, brush cleaners, etc.) for paints or other similar surface-coating materials (such as varnishes and lacquers), that contain 10 percent or more by weight of benzene (also known as benzol), toluene (also known as toluol), xylene (also known as xylol), petroleum distillates (such as gasoline, kerosene, mineral seal oil, mineral spirits, naphtha, and Stoddard solvent, etc.), or combinations thereof, and that have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(16) *Acetaminophen.* Preparations for human use in a dosage form intended for oral administration and containing in a single package a total of more than one gram acetaminophen shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following—

(i) Effervescent tablets or granules containing acetaminophen, provided the dry tablet or granules contain less than 15 percent acetaminophen, the tablet or granules have an oral LD–50 of 5 grams or greater per kilogram of body weight, and the tablet or granules contain no other substance subject to the provisions of this section.

(ii) Unflavored acetaminophen-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 13 grains of acetaminophen per unit dose and that contain no other substance subject to this § 1700.14(a).

(17) *Diphenhydramine.* Preparations for human use in a dosage form intended for oral administration and containing more than the equivalent of 66 mg diphenhydramine base in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), if packaged on or after February 11, 1985.

(18) *Glue removers containing acetonitrile.* Household glue removers in a liquid form containing more than 500 mg of acetonitrile in a single container.

(19) *Permanent wave neutralizers containing sodium bromate or potassium bromate.* Home permanent wave neutralizers, in a liquid form, containing in single container more than 600 mg of sodium bromate or more than 50 mg of potassium bromate.

(20) *Ibuprofen.* Ibuprofen preparations for human use in a dosage form intended for oral administration and containing one gram (1,000 mg) or more of ibuprofen in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(21) *Loperamide.* Preparations for human use in a dosage form intended for oral administration and containing more than 0.045 mg of loperamide in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(22) *Mouthwash.* Except as provided in the following sentence, mouthwash preparations for human use and containing 3 g or more of ethanol in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c). Mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single

unit are exempt from this requirement. The term "mouthwash" includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

(23) *Lidocaine.* Products containing more than 5.0 mg of lidocaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(24) *Dibucaine.* Products containing more than 0.5 mg of dibucaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(25) *Naproxen.* Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(26) *Ketoprofen.* Ketoprofen preparations for human use and containing more than 50 mg of ketoprofen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b) and (c).

(27) *Fluoride.* Household substances containing more than the equivalent of 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c).

(28) *Minoxidil.* Minoxidil preparations for human use and containing more than 14 mg of minoxidil in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c). Any applicator packaged with the minoxidil preparation and which it is reasonable to expect may be used to replace the original closure shall also comply with the provisions of § 1700.15(a), (b) and (c).

(29) *Methacrylic acid.* Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

(30) *Over-the-Counter Drug Products.* (i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) of this section to be in special packaging, shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products approved for OTC marketing based on an application for OTC marketing submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an OTC drug product remains in effect.

(ii) For purposes of this paragraph (30), *active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and *drug product* means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 (2001) and 21 CFR 314.3 (2000), respectively.)